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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/591,100

10/25/2006

Immanuel Straub

516/12

6349

27538 7590 03/01/2010

GIBSON & DERNIER LLP
900 ROUTE 9 NORTH
SUITE 504
WOODBIDGE, NJ 07095

EXAMINER

EASTWOOD, DAVID C

ART UNIT

PAPER NUMBER

3731

MAIL DATE

DELIVERY MODE

03/01/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/591,100	Applicant(s) STRAUB, IMMANUEL	
	Examiner DAVID EASTWOOD	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 January 2010.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-49 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-49 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 30 August 2006 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/15/2010</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Response to Amendment

Receipt is acknowledged of applicant's amendment filed 1/15/2010. Claims 1-21, 23 and 24 have been canceled without prejudice. Claims 26-49 are pending and an action on the merits is as follows.

Applicant's arguments with respect to claims 1-21, 23 and 24 have been considered but are moot in view of the new ground(s) of rejection.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. The factual inquiries set forth in *Graham v. John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

3. Claims 26-34, 36-45 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al. (US 5873882) (hereafter Straub) in view of Kocak (US 4705511).

Regarding claims 26 and 47, Straub discloses a catheter comprising a flexible tube (12,22), said flexible tube having a proximal end, said flexible tube having a distal end (fig. 1), a working head (catheter portion depicted in fig. 2), said working head having a proximal end, said working head having a distal end (fig. 1 and 2), said proximal end of said working head being connected to said distal end of said tube (fig. 2) said working head having a cylindrical bore open from said proximal end of said working head (bore depicted in fig. 7), said working head having an end wall capping (where cap is defined as summit; top; acme. cap. (n.d.). *Dictionary.com Unabridged*. Retrieved February 25, 2010, from Dictionary.com website: <http://dictionary.reference.com/browse/cap>) said cylindrical bore at said distal end of said working head (annular end wall at the utmost distal end ,or summit/top, of element 14 depicted in fig. 6 and 7), a guide wire (24) extending through said tube and through said cylindrical bore (fig. 1 and 7), and said guide wire extending out of a hole in said end wall of said working head (fig. 7), a flexible transport screw (32) extending from said proximal end of said tube through said tube to said distal end of said working head (fig.7)(C4 L1-7), said flexible transport screw provided with helically extending transport surfaces (fig. 8), said flexible transport screw connected to a rotary drive configured to rotate said flexible transport screw (C3 L23-28 and C4 L3-7), said flexible transport screw having a proximal end (C3 L23-28 and C4 L3-7), and said flexible transport screw

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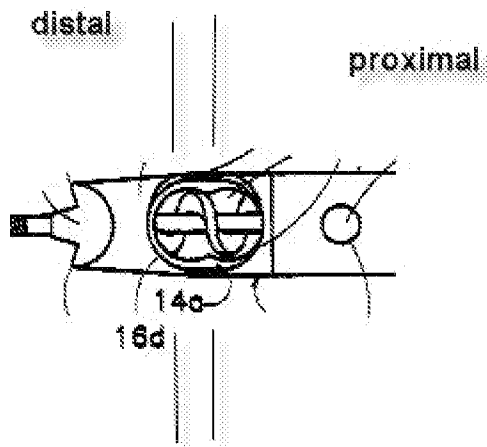
having a distal end configured to rotate relative to said end wall (element 32 rotates relative to element 14 C4 L1-15), wherein said distal end abuts said end wall (an annular portion of screw portion 32 abuts the end wall as defined above and as seen in fig. 6 and 7), said flexible transport screw having a distal part disposed in said cylindrical bore (fig. 7), said flexible transport screw distal part forming a helix (fig. 7), said helix having an external diameter, fitting the diameter of said cylindrical bore to rotate therein in contact therewith (fig. 8), said flexible transport screw distal part having sharp edges (fig. 8), a first lateral opening in said working head (fig. 6 and 7), said first lateral opening having internal edges in contact with said flexible transport screw distal part edges to shear and comminute material (as screw 32 and rotor 16 rotate screw 16 passes across shearing surface 14 a,b,c shearing material and commuting said material), said helical transport surfaces removing material in a direction towards the proximal end of said tube (C4 L1-7 and fig. 1), said flexible tube distal end having a proximate flexible tube distal end portion (see proximate distal end portion of flexible tube 12,22 depicted in fig. 7), said flexible tube distal end portion is connected to a recess in said working head proximal end (C4 L57-62 and fig. 7).

Straub fails to disclose said flexible tube distal end portion including a helical spring, said helical spring encased in a thin-walled plastic sheath. However, Kocak discloses a flexible tube including a helical spring, said helical spring encased in a thin-walled plastic sheath (see fig. 1 and 2 of Kocak). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub with the

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reinforcement means as disclosed by Kocak. Doing so would reinforce the flexible tube of Straub reducing the risk of kinking as taught by Kocak (C1 L28-35).

Regarding claim 27-34, Straub discloses said helix external diameter exactly fits said cylindrical bore's diameter to permit only minimal diameter play (see depiction of bore and helix depicted in fig. 7), said working head has an external surface (see external surface depicted in fig. 2-3), and said working head external surface tapers at said working head distal end (see distal end of working head depicted in fig. 2), said first lateral opening internal edges are sharp (C4 L10-12), said working head has an external surface, said first lateral opening has external edges at said external surface; and, said external edges are rounded (see rounded edges of lateral opening depicted in fig. 2 and 3), said lateral opening is a slot (see fig. 3 and where slot is defined as a narrow, elongated depression, groove, notch, slit, or aperture, esp. **a narrow opening for receiving or admitting something**, as a coin or a letter, slot. (n.d.). *Online Etymology Dictionary*. Retrieved February 25, 2010, from Dictionary.com website: <http://dictionary.reference.com/browse/slot>), said slot runs at least partially in an axial direction of said working head (fig. 3), said slot is formed at least partly along a helix relative to a longitudinal axis of said working head (fig. 3 and description above), said slot has width decreasing towards a proximal end of said working head (see figure below where the slot or opening as a portion decreasing towards a proximal end)



Regarding claims 36 and 38-45, Straub discloses said working head has a distal end region proximate to said working head distal end (as depicted in fig. 2 and 3), said working head has an external surface (see external surface depicted in fig. 2 and 3), a groove-like bottomed recess (section between the outer portion of item 14's annular wall and component 16's lateral opening) in said working head external surface (fig. 3 and 6), said groove-like recess extending from said working head distal end region to open into said lateral opening (as depicted in fig. 3), a width of said groove-like bottomed recess is greater than a chord of an internal diameter of said working head (since the bottom surface of the groove-like recess is the outer surface of component 14, which lies within component 16, that it must have a width greater than a chord of an internal diameter of said working head since the internal diameter of said working head is the inner surface of item 14), said slot is formed at least partly along a helix relative to a longitudinal axis of said working head (as depicted in fig. 2 and 3), the connection between said flexible tube distal end portion and said recess in said working head

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proximal end resists tension and pressure (Column 4 lines 57-62), at least one tube reinforcement (outer surface of element 32 abutting the annular wall of the flexible tube) in said flexible tube, said tube reinforcement is a metallic helix (Column 4 Lines 52-56), said tube reinforcement is arranged on an inside of said tube (fig. 7), said working head is made of metal (Column 4 Lines 52-56), said flexible transport screw is made of metal (Column 4 Lines 52-56).

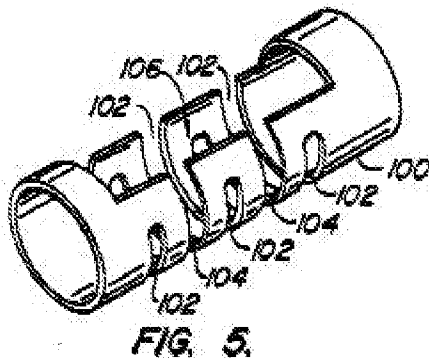
Regarding claim 37, Straub and Kocak fail to disclose the depth of said groove-like bottomed recess increases in the direction from said working head distal end to said working head proximal end. However, it would have been an obvious matter of design choice to independently taper the cooperative surfaces of element 14 and 16 such that the depth of said groove-like bottomed recess increases in the direction from said working head distal end to said working head proximal end, since applicant has not disclosed that such a modification solves any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing an opening or guider to an aperture of a ablating catheter. In re Dailey and Eilers, 149 USPQ 47 (1966).

4. Claim 35 and 48-49 is rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al (US 5873882) in view of Kocak (US 4705511) as applied to claim 26-34 above and further in view of Evans et al (US 5312425) (hereafter Evans).

Regarding claim 35 and 48, the invention of Straub as modified by Kocak discloses the claimed invention except for said slot is formed in an L-shape, said first lateral opening forming an L- shaped slot, said slot having a first limb extending

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substantially in a longitudinal direction and said slot having a second limb extending along a part of a circumference. However, Evens discloses an L-shaped slot for a working end, said slot having a first limb extending substantially in a longitudinal direction and said slot having a second limb extending along a part of a circumference (see figure 5 and below)



item 102: Circumference limb of L-shaped slot
item 106: Longitudinal limb of L-shaped slot

It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub and Kocak with the L-shaped slot as disclosed by Evans. Doing so would provide a greater cutting surface area increasing the efficiency of the device allowing the device to remove more tissue at any given moment. Furthermore, since applicant has not disclosed that such solve any stated problem or is anything more than one of numerous shapes or configurations a person ordinary skill in the art would find obvious for the purpose of providing a tissue receiving slot for a working end of an ablating catheter. In re Dailey and Eilers, 149 USPQ 47 (1966).

Regarding claim 49, the invention of Straub, Kocak and Evans discloses the claimed invention except for explicitly stating that a ratio of a width of the first limb extending in the longitudinal direction to a width of the second limb extending along a part of a circumference is from 1.0 to 1.3. However, it would have been obvious to one having ordinary skill in the art at the time the invention was made to Construct the L-shaped slot with a ratio of a width of the first limb extending in the longitudinal direction to a width of the second limb extending along a part of a circumference is from 1.0 to 1.3, since it has been held that discovering an optimum value of a result effective variable involves only routine skill in the art. In re Boesch, 617 F.2d 272, 205 USPQ 215 (CCPA 1980).

5. Claim 46 is rejected under 35 U.S.C. 103(a) as being unpatentable over Straub et al. (US 5873882) and Kocak (US 4705511) as applied to claim 26-34 and 36-45 above in view of Clement et al. (US 6565588) (hereafter Clement).

Regarding claim 46, the invention of Straub and Kocak discloses the claimed invention except for said working head includes ceramic material. However, Clement discloses a working end manufactured with Ceramic components (C11 L42-45). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the invention of Straub and Kocak with the manufacturing material as disclosed by Clement. Doing so would provide a more inexpensive end product. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to manufacture the device of Straub and Kocak with ceramic components, since it has been held to be within the general skill of a worker in the art to select a

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known material on the basis of its suitability for the intended use as a matter of obvious design choice. In re Leshin, 125 USPQ 416.

Conclusion

6. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to DAVID EASTWOOD whose telephone number is (571)270-7135. The examiner can normally be reached on Monday thru Friday 9 a.m. to 5 p.m..

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571)272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/DAVID EASTWOOD/
Examiner, Art Unit 3731

/Gary Jackson/
Supervisory Patent Trainer
Art Unit 3700